

Remarks

Amendments to Claims.

The specification and claims have been amended in accordance with the proposed revisions to 37 C.F.R. 1.121 as set forth in 1267 OG 106 (25 February 2003).

Claims 1-19 have been cancelled and replaced with new claims 20-39. The reason for doing this is due to the multiple-dependent nature of many of the claims. As will become apparent, amending the claims (rather than replacing them with a new set of claims) would have resulted in non-compliant multiple-dependent numbering. The new claims generally correspond to the (now cancelled) original claims as follows:

<u>New claim</u>	<u>Original claim</u>
20	1 (amended)
21	2 (original)
22	3 (original)
23	4 (original)
24	5 (original)
25	6 (original)
26	7 (amended)
27	7 (amended)
28	7 (amended)
29	8 (original)
30	9 (original)
31	10 (original)
32	11 (amended)
33	12 (original)
34	13 (original)
35	14 (original)
36	15 (original)
37	16 (original)
38	17 (amended)
39	18 (amended)

1 New claims corresponding to "original" claims have been amended only to
2 correct the dependency numbering to reflect the new claim numbers.

3 Objections to the Specification

4 The specification was objected to because "it is unclear (page 5, line 36) how the
5 'kiss-cut' function is provided." It was further stated that, [a]dditional clarification and
6 explanation is required."

7 In response, the paragraph beginning at page 5, line 36, and ending at page 6,
8 line 3 of the specification has been amended by adding, following the first sentence (i.e.,
at line 1, page 36, following - -at this stage--), the following new sentence:

9 - -For example, a die can be used to cut through the disposable layer,
10 allowing the disposable layer to be peeled away from the layer of
11 adhesive at the "kiss-cut".- -

12 The expression "kiss-cut" is an expression well understood in the art of
13 manufacturing multi-layer flexible films and sheets. In support of this position, the
14 Applicant has attached hereto Internet web page printouts from three different web sites.
15 The relevant portions of each printout have been highlighted to assist the Examiner.
16 The first printout (consisting of 3 pages) is a glossary of terms from the Atlantic Gasket
17 Corporation of Philadelphia, Pennsylvania. At the second page of the printout, a
18 definition of "kiss-cut" is provided. ("Die-cutting material so that it stays in roll form. The
19 finished pieces are easily peeled from the release liner.") ("Release liner" is defined at
20 the bottom of page 2.) The second printout (consisting of 2 pages) is a Service Bulletin
21 describing how to make a "kiss-cut" using the "System 300" offered for sale by Ioline
22 Corporation of Woodinville, Washington. On the first page a description is provided of
23 what constitutes a "kiss-cut". ("Kiss cutting is the process of cutting through one layer of
24 a stack of material and not cutting through the layer(s) below. Typically the upper
25 layer(s) has a pressure sensitive backside which adheres to the lower layer of material.")
The third printout (consisting of one page) describes an apparatus offered for sale by Die
Craftsmen International of Kitchener, Ontario, Canada that can perform kiss-cutting. The
Applicant believes that these references fully support the language added to the
specification, and therefore respectfully request that the objection to the specification be
removed.

1 Objections to the Claims

2 Claims 1, 4, 7, 11, 13 and 19 have been objected to for the reasons stated in
3 paragraph 4 (page 2) of the Office action.

4 New claims 20, 23, 32 and 34 correspond to original claims 1, 4, 11 and 13, as
5 indicated above; new claims 26 through 28 correspond to original claim 7; original claim
6 19 has no corresponding new claim.

7 In response, new claim 1 has been amended over original claim 1 to recite that
8 the pouch has "an open edge" (see line 15 of new claim 20), thereby adding antecedent
9 basis of "the previously opened edges".

10 Claim 7 has been cancelled, and is replaced with new claims 26-28 which remove
11 the alternate claiming language.

12 New claim 32 has been amended over original claim 11 to remove the ambiguity
13 of "the or" at line 3.

14 With respect to claim 34 (corresponding to original claim 13), the Applicant
15 contends that the claim is definite, as originally presented. Claim 34 depends from claim
16 31; claim 31 recites, "transverse sealing devices". Accordingly, "the transverse sealing
17 devices" recited in claim 13 finds antecedent basis support in claim 10.

18 Claim 19 has been cancelled, and therefore the objection with respect to this
19 claim is now moot.

20 The Applicant contends that new claim 23 (corresponding to original claim 4) is
21 definite (as regards the meaning of "kiss-cut") in light of the amendment to specification
22 (as set forth above), as well as in light of the fact that "kiss-cut" is a term well understood
23 in the art (as also explained above).

24 For the reasons stated above, the Applicant respectfully requests that the
25 objections to the indicated claims be removed.

26 Further Amendments to the Claims

27 In addition to the amendments to the claims in light of the objections to the
28 claims, the Applicant has made the following further amendments to the indicated new
29 claims over their original counterparts: Claims 20, 38 and 39 (corresponding to
30 respective original claims 1, 17 and 18) now recite "a gel" as an alternative to "the liquid".
31 Support for this amendment is found in the specification at page 2, lines 23 through 35,
32 and page 6, line 18.

1 Rejection of Claim 19 under 35 U.S.C. 102

2 Claim 19 has been rejected under 35 U.S.C. 102 as being anticipated by U.S.
3 patent No. 4,769,974 (Davis).

4 Claim 19 has been cancelled. There is no new counterpart to original claim 19.
Accordingly, the rejection of this claim is now moot.

5 Rejection of Claims 1-18 under 35 U.S.C. 103(a)

6 Claims 1-18 have been rejected under 35 U.S.C. 103(a) as being unpatentable
7 over U.S. Patent No. 4,769,974 (Davis) in view of U.S. Patent No. 5,646,285 to
8 (Sablotsky et al.).

9 The Applicant contends that new claims 20-39 (corresponding to original claims
10 1-18, as set forth above) are not obvious over Davis in view of Sablotsky et al., for
11 reasons that will be explained below.

12 The Examiner contends that Davis discloses all of the claimed elements of
13 original claim 1 (new claim 20), except that Davis does not disclose a first, multi-layered
14 strip or a cutting cylinder for lateral separation of the pouches. The Examiner contends
15 that Sablotsky et al. teach the use of a multi-layered strip having a backing layer, an
16 adhesive layer, and a release layer to form transdermal patches, and a cutting cylinder
for the purpose of making transdermal patches in a singular and continuous mechanical
motion.

17 As a starting point, MPEP 706.02(j) states:

18 "[t]o establish a *prima facie* case of obviousness, three basic
19 criteria must be met. First, there must be some suggestion or
motivation, either in the cited references themselves or in the
knowledge generally available to one of ordinary skill in the art, to
modify the reference or to combine the reference teachings.
20 Second, there must be a reasonable expectation of success.
21 Finally, the prior art reference (or references when combined)
22 must teach or suggest all the claim limitations. The teaching or
23 suggestion to make the claimed combination and the reasonable
24 expectation of success must both be found in the prior art and not
25 based on applicant's disclosure." (Emphasis added.)

1 The Applicant contends that claim 20 is patentable over Davis in view of
2 Sablotsky et al. because not all of the above-referenced conditions for obviousness are
3 met. Specifically, the Applicant contends that there is no suggestion or motivation, either
4 in the references themselves or in the knowledge generally available to one of ordinary
5 skill in the art, to modify the references or to combine the teachings to result in what is
6 contained in claim 20. Applicant's claim 20, which is directed towards, "[a] continuous
7 process for forming a transdermal patch" (emphasis added) includes the following
8 limitation:

9 "introducing one of a liquid or a gel containing an active substance
10 into the pouch or pouches, once formed" (emphasis added).

11 Davis discloses filling and sealing bags with food stuffs. Sablotsky et al. disclose
12 methods and apparatus for formation of matrix transdermal patches. ("Matrix"
13 transdermal patches (as they are known in the art) are quite different from the
14 transdermal patches of Applicant's claim 1, in that a matrix transdermal patch supports
15 the active ingredient or drug on a pressure sensitive layer, which is then joined to a
16 release layer to form the matrix transdermal patch. See Sablotsky et al., column 3 lines
17 39-50.) Applicant's transdermal patch, on the other hand, is not a matrix-type
18 transdermal patch, but is a liquid- or gel-filled transdermal patch. Applicant's
19 transdermal patch is formed by first forming the multi-layered pouch, then filling the
20 pouch with a liquid or a gel containing an active substance, and thereafter sealing the
21 pouch.

22 Davis does not teach or suggest using the method disclosed therein for any
23 purpose other than for food stuffs, and certainly not for transdermal patches. Sablotsky
24 et al. do not teach or suggest using the method disclosed therein for liquid or gel
25 transdermal patches – only for matrix transdermal patches. That is, neither reference
mentions liquid or gel fill transdermal patches. It is therefore improper for these
references to be combined to deny patentability to the Applicant's claims.

26 As set forth in the MPEP at section 2143.01, "[o]bviousness can **only** be
27 established by combining or modifying the teachings of the prior art to produce the
28 claimed invention where there is some teaching, suggestion, or motivation to do so
29 found either in the references themselves or in the knowledge generally available to one
30 of ordinary skill in the art." (Emphasis added.) As just indicated, there is certainly no
teaching or suggestion in the references to combine the references, as the Examiner

1 suggests. Further, “[t]he mere fact that the references can be combined or modified
2 does not render the resultant combination obvious unless the prior art also suggests the
3 desirability of the combination.” (MPEP, section 2143.01; emphasis added.) The
4 Applicant has carefully reviewed the references and can find no such suggestion therein
5 of the desirability to combine the references. The Applicant therefore respectfully
6 requests that the Examiner either cite to the specific location in either or both of the
7 references where such a suggestion is made, or withdraw the rejection.

8 As to whether one of ordinary skill in the art would have been motivated to make
9 the proposed modification absent any teaching or suggestion in the references
10 themselves, MPEP section 706(j) instructs Examiners to provide “an explanation why
11 one of ordinary skill in the art at the time the invention was made would have been
12 motivated to make the proposed modification.” (Emphasis added.) No such explanation
13 was provided in the Office action. In fact, the Applicant contends that one of ordinary
14 skill in the art at the time the invention was made would NOT have been motivated to
15 make the proposed modification, for the following reasons.

16 As described in the Applicant’s specification at page 2, lines 4-22, the prior art
17 method of manufacturing transdermal patches containing a liquid or a gel is as follows:

- 18 • a multi-layer laminate is first formed;
- 19 • the laminate is placed in a horizontal position, and a liquid or a gel is deposited
20 along the laminate at discrete points; and
- 21 • a backing material is then placed over the liquid- or gel- supporting laminate and
22 sealed to the laminate in areas where there is no liquid or gel.

23 One of ordinary skill in the art (at the time the invention was made) would not
24 have considered applying the food pouch methods described by Davis to manufacturing
25 of transdermal patches. Specifically:

26 (1) Prior art liquid- or gel-filled transdermal patches were not manufactured by
27 forming and filling pouches, but by the overlay method described above. Accordingly,
28 one would look to other overlay technologies for transdermal patches, and not to non-
29 overlay technology.

30 (2) Pouch filling and sealing technology was known for food stuffs, but not for
31 liquids or gels used in transdermal patches. Accordingly, one would not look to pouch
32 technology for a traditionally non-pouch product. And;

(3) The food pouches of Davis are intended to be impermeable. Unless the film is torn or cut along one edge, the contents of the pouch will not be released. Contrarily, with a transdermal patch, the liquid or gel is intended to migrate through a permeable membrane in the patch. Put simply, impermeable food pouch technology would not have been considered as appropriate for use with permeable transdermal patches.

The following chart should further illustrate why one skilled in the art of liquid- and gel-filled transdermal patches would not consider Davis:

	Applicant's Technology	Davis
Use:	Transdermal patches	Food storage
Substance contained in package:	Drugs and pharmaceuticals in liquid or gel form	Food stuffs
Substance dispensed by:	Permeable membrane in film	Tearing or cutting end of pouch
Film type:	a) Multi-layer; b) Permeable	a) Single-layer; b) Impermeable
Manufacturing method (prior art method at time of Applicant's invention):	Overlay method: a) Provide multi-layer film; b) Deposit gel on film; c) Place cover layer over gel; d) Seal cover layer to film.	Form-and-fill method: a) Provide 2 single layer films; b) Seal film on 3 sides to form pouch; c) Fill pouch with food; d) Seal pouch.

As can be seen, food pouch technology and liquid/gel transdermal patch technology **do not share a single common element** which would lead one of skill in the art of liquid- and gel-filled transdermal patches to consider the food pouch technology of Davis in seeking to manufacture a liquid- or gel-filled transdermal patch.

Likewise, one of ordinary skill in the art (at the time the invention was made) would not have considered using the matrix transdermal patch method of Sablotsky et al. for a liquid- or gel-filled transdermal patch, since the method and apparatus described in Sablotsky is unworkable for liquid or gel patches. Specifically, the matrix patches of Sablotsky et al. are formed by feeding a multi-layered web through a stack of rollers (items 86, 92 and 96 of Sablotsky's Fig. 4) and a section cutter (30, Fig. 4) for cutting out the patches. Such a mechanism would not be suitable for filling, forming and cutting the liquid- or gel-filled transdermal patches of the Applicant's invention. That is, the rollers used in Sablotsky's apparatus would burst the pouches of the Applicant's invention. And there is no teaching or suggestion in Sablotsky et al. to modify the disclosed apparatus to accommodate liquid- or gel-filled transdermal patches.

1 As set forth in MPEP § 2141 ("BASIC CONSIDERATIONS WHICH APPLY TO
2 OBVIOUSNESS REJECTIONS"):

3 "When applying 35 U.S.C. 103, the following tenets of patent law
4 **must** be adhered to:

5 (A) The claimed invention must be considered as a whole;
6 (B) The references must be considered as a whole and **must**
7 suggest the desirability and thus the obviousness of making the
8 combination;
9 (C) The references must be viewed without the benefit of
10 impermissible hindsight vision afforded by the claimed invention; and
11 (D) Reasonable expectation of success is the standard with which
12 obviousness is determined.

13 (Emphasis added.)

14 The Applicant contends that the rejection of the claims as being obvious over
15 Davis in view of Sablotsky et al. fails on at least three counts under this mandate.
16 Specifically:

17 1) neither of the references suggest the desirability of making the
18 combination (as described above);
19 2) claim 1 was used as a "roadmap" to find the Davis reference
20 ("impermissible hindsight reconstruction") since (as described at length above),
21 Davis had no common features with liquid- or gel-filled transdermal patch
22 technology at the time the invention was made; and
23 3) there would be no reasonable expectation of success since the
24 roller stack of Sablotsky et al. would burst a liquid- or gel-filled transdermal patch.

25 For these reasons the Applicant contends that claim 20 is novel and non-obvious
over Davis in light of Sablotsky et al. It is a well known axiom of patent law that "[i]f an
independent claim is nonobvious under 35 U.S.C. 103, then any claim depending
therefrom is nonobvious" (MPEP, section 2143.03). Accordingly, claims 21 through 39,
all of which depend from either directly or indirectly from claim 20, are also allowable.
The Applicant therefore respectfully requests that the rejection of the claims under 35
U.S.C. 103 be withdrawn and that claims 20 through 39 be allowed.

Fee for Additional Claims

The fee for two (2) additional dependent claims beyond those originally paid for is enclosed herewith.

Request for Extension of Time under 37 C.F.R. § 1.136(a)

The applicant hereby requests a one (1) month extension of time under 37 C.F.R. § 1.136(a) to respond to the current Office action, to and through March 25, 2003. The fee for the one month extension is enclosed herewith.

Summary

The Applicant believes that this response constitutes a full and complete response to the Office action, and therefore requests timely allowance of the claims.

If the next Office action is anything other than a Notice of Allowance for claims 20 through 39, the below-signed attorney respectfully requests that the Examiner call him before issuing the action.

Respectfully submitted,

Mark Rupert TUCKER

Date: March 24, 2003

By John

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A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

ACCELERATED AGING: Simulated aging designed to predict the performance of an adhesive after natural aging, typically by using heat, UV radiation and moisture alone or in combination.

ACRYLIC ADHESIVE: Adhesive made from acrylic monomers that have been polymerized. They have good resistance to UV radiation, plasticizer and extreme temperatures.

BLOOM: A coating or efflorescence creating a discoloration or change in appearance of the surface of a rubber product caused by the migration of a liquid or solid to the surface. Examples: Sulfur Bloom, Wax Bloom. Not to be confused with dust on the surface from external sources.

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BLOWING AGENT: Mixed with a rubber compound, this material decomposes when heated to form the gases that create sponge rubber.

CELLULAR RUBBERS: Rubber products that contain cells or small hollow receptacles. The cells may either be open or interconnecting or closed and not interconnecting.

CI: The abbreviation for cloth-inserted, indicating a sheet of rubber containing one or more plies of fabric covered with rubber.

CLOSED CELL: A cell totally enclosed by its walls and hence not interconnecting with other cells.

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COMPOUND: An uncured mixture of a rubber polymer and other ingredients (fillers, vulcanizing agent, etc.).

COMPRESSION SET: The deformation which remains in rubber after it has been subjected to and released from a specific compressive stress for a definite period of time at a prescribed temperature. Compression set measurement is for the purpose of evaluating creep and stress relaxation properties of rubber.

CONFORMABILITY: The ability of an adhesive tape to mold itself to the shape of an object without wrinkling or creasing.

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CREEP RELAXATION: In a flange gasket, loss of stress accompanied by constantly decreasing compressed thickness. This type of relaxation is encountered in bolted flange joints.

CROSSLINKED: The establishment of a chemical bond between the molecular chains of a given polymer, thereby enhancing physical properties.

DENSITY: The weight per unit volume of a material – usually expressed in PCF (pounds per cubic foot).

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DOUBLE-COATED: Tape with adhesive on both sides.

DUROMETER: An instrument for measuring the indentation hardness of rubber; also, sometimes used as a synonym for hardness.

ELASTOMER: A macromolecular material which, in the vulcanized state, at room temperature can be stretched repeatedly to at least twice its original length and which, upon release of the stress, will immediately return to approximately its original length.

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ELONGATION: An increase in length expressed numerically as a fraction or percentage of the initial length.

EXPANDED RUBBER: Cellular rubber having closed cells made from a solid rubber compound.

GASKET (Mechanical): A deformable material clamped between essentially stationary faces to prevent the passage of matter through an opening or joint.

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KISS-CUT: Die-cutting material so that it stays in roll form. The finished pieces are easily peeled from the release liner.

LAMINATE: Product made by bonding together two or more layers of like, or unlike materials.

LINER SIDE: The adhesive side covered by the release liner.

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MILS: Thousandths of an inch.

MONOMER: A simple chemical compound that enters into the production of a polymer.

OPEN CELL: A cell not totally enclosed by its walls and hence interconnecting with other cells.

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PATTERN COATING: Adhesive applied in patterns in the machine direction causing alternating bands of adhesive and non-adhesive areas.

PLASTICIZER: A material which, when incorporated in rubber or a polymer, will change its hardness, flexibility, process-ability and plasticity.

POLYMER: Material made from chains of identical molecules (monomers). The basis of most plastics and adhesives.

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PRESSURE SENSITIVE: Adhesive that can be applied to a substrate by using light pressures.

RELEASE LINER: Coated paper applied to the adhesive to protect it until ready for use.

REMOVABLE ADHESIVE: Adhesive that can be removed from a surface without leaving a residue.

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RUBBER: A material that is capable of recovering from large deformations quickly and forcibly, and can be, or already is, modified to a state in which it is essentially insoluble (but can swell) in boiling solvent, such as benzene, methyl ethyl ketone, and ethanol-toluene azeotrope. A rubber in its modified state, free of diluents, retracts within 1 minute to less than 1.5 times its original length after being stretched at room temperature (18 to 29°C) twice its length and held for 1 minute before release.

RUBBER BASED ADHESIVE: Made from natural and synthetic rubber compounds. They have excellent initial tack but low temperature and aging resistance.

SILICONE ADHESIVE: Adhesives made from silicone polymers that have excellent high temperature resistance.

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SPONGE RUBBER: Cellular structure produced by adding gasifying substance to rubber compound, expanding and curing in heated mold. Cells may be open (interconnecting) or closed.

SURFACE ENERGY: Characteristic of a substrate surface affecting bonding of an adhesive. The higher it is, the better an adhesive bonds. Can be increased by Corona treatment.

TACK: The stickiness of a tape.

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TENSILE STRENGTH: The maximum tensile stress applied while stretching a specimen to rupture.

THERMOPLASTIC RUBBER: Rubber that does not require chemical vulcanization and will repeatedly soften when heated and stiffen when cooled; and which will exhibit only slight loss of its original characteristics.

THERMOSETTING RUBBER: Chemically vulcanized rubber that cannot be remelted or remolded without destroying its original characteristics.

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TRANSFER TAPE: An unsupported adhesive on a liner.

UL94: Underwriters Laboratory's rating for flame spread.

VULCANIZATION: An irreversible process during which a rubber compound through a change in its chemical structure (for example, cross-linking) becomes less plastic and more resistant to swelling by organic liquids and elastic properties are conferred, improved, or extended over a greater range of temperature.

WATER ABSORPTION: Measurement of water absorbed by flexible cellular materials during submersion in water under pressure.



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Bulletin # 20
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Service Bulletin for the System 300

How to "KISS-CUT"

Kiss cutting is the process of cutting through one layer of a stack of material and not cutting through the layer(s) below. Typically the upper layer(s) has a pressure sensitive backside which adheres to the lower layer of material.

Kiss cutting creates more scrap material for the upper layer(s), (compared to cutting individual layers and hand placing them on the lower layers) but can result in a considerable time savings since multiple layers do not need to be aligned and the placement stitch for the upper layer may be eliminated from the embroidery process.

1. Place Background material onto adhesive sheet and smooth it flat. Place the foreground material on top of the background material making sure the sticky side is down.
2. Load *Blade Holder* into *Carriage Jaw*.
3. Adjust *Blade Holder* as described in the quick start guide. (Test with single button test cut.) Adjust blade exposure and cutting force so that only the material is cut. Adhesive sheet may be scored lightly.

Note: It is recommended that the materials are of similar type and thickness so the blade does not need readjustment.

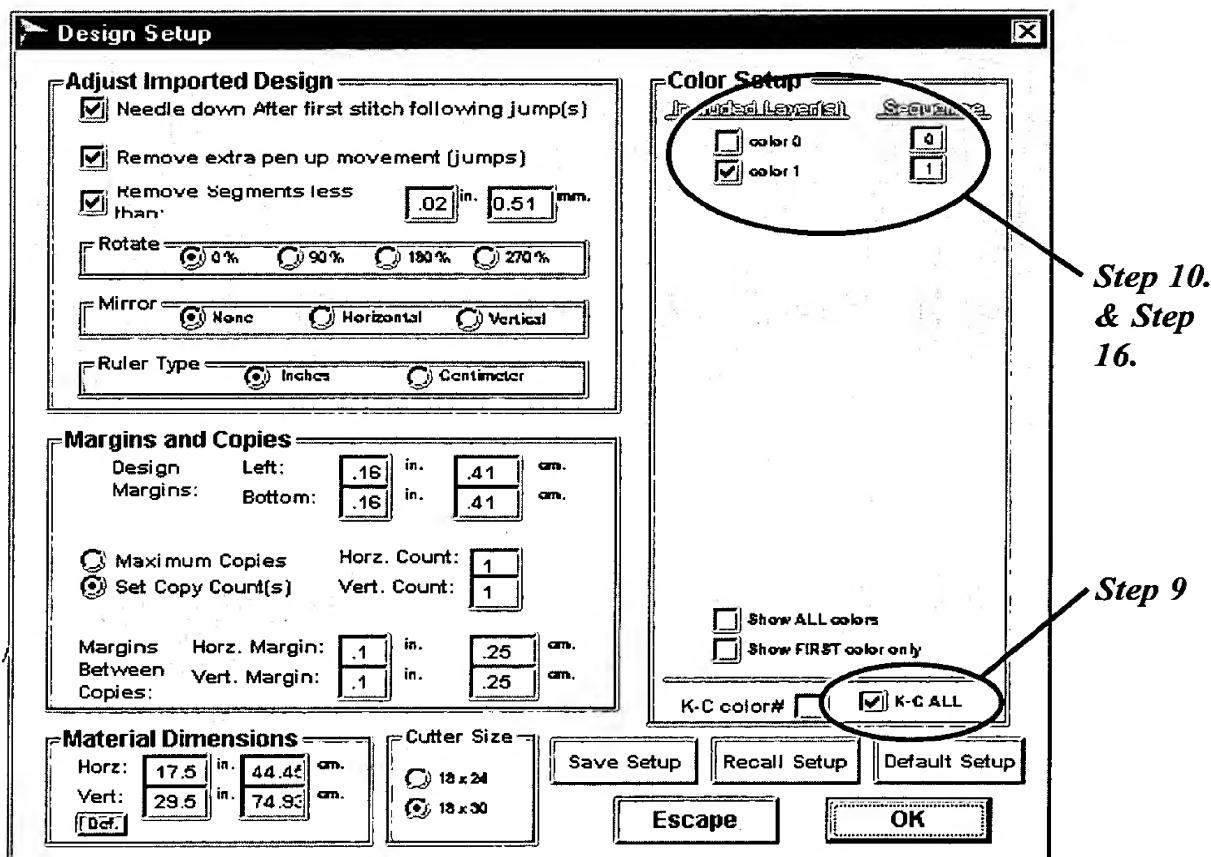
4. Once blade is adjusted, use the *Keypad Arrow* keys to position the *Table* and *Carriage* so that the *Blade Holder* is over the lower right corner of the material (lower left origin of plot file).
5. Press **Set Origin** on the *Keypad* to obtain a green *Keypad* light.
6. Open the 301 software.
7. Select the directory and file you wish to open. Double click on the file or select the file and click on **Load Import File**.
8. Select **Design Setup**.
9. Under the **Color Setup** heading, select **K-C ALL** (Kiss Cut All). (*See Design Setup window on page 2*)
10. Under the **Color Setup** heading, select the color that corresponds to the "Top" layer of the design to be cut. This should be the profile with the Smallest perimeter. (*See Design setup window on page 2*)
11. Select **OK**.
12. Select **Send to Cutter**.
13. Select **OK**.
14. When the first cut is done, press the **Start/Stop** button (the light should turn "Red") and

How to "KISS-CUT" (Cont...)

move the tray forward. Weed away the excess material around the top letter.

15. Press **Start/Stop** button on the cutters keypad, the light should turn back to green, and the tray and head will move back to the original starting point.
16. Under the **Color Setup** heading, select the color that corresponds to the next layer of the design to be cut and deselect the color that was just cut. This profile should have a larger perimeter than the one previously cut.
17. Select **OK**.
18. Select **Send to Cutter**.
19. After it has finished cutting, weed away the excess material.

Note: As an alternative method, you can also cut the pieces in reverse order. For example, cut out the background piece(s) first, then lay the top piece of fabric on and cut those pieces out. This method allows you to cut a whole tray of Kiss-Cuts, and weed the two pieces of fabric together.



Ioline 301 "Design Setup" Window

Welcome
March. 22nd

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**Home****Mission Statement****History****Products****Contact****Online Order**

Kiss Cut Trimming

We specialize in building three-dimensional trimming tools that are called "Kiss Cut Trimming" tools or "Contour" dies. The name contour comes from the way the tool is built. These types of tools consist of a series of blades (knives) that are hand finished to the exact shape of the part. Materials that can be cut from this process are Carpet, Vinyl, Rubber, PVC, and very thin plastics.



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» Steel Types	» Single Edge Dies	» Double Edge Dies	» Cut and Perforation Dies
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» Versa Nest Dies	» Serrated Edge Dies	» Hand Punches	» Finishing

Contour Dies

» BY-PASS Dept	» Kiss Cut Trimming	» Contour & Bypass additional Equipment
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